

OBERMAYER REBMANN MAXWELL & HIPPEL LLP

By: Steven A. Haber, Esquire
1120 Route 73, Suite 420
Mount Laurel, NJ 08054-5108
Phone: (856) 795-3300
Email: steven.haber@obermayer.com

*Attorneys for Amici Curiae
Ryan White Clinics for 340B Access,
Little Rivers Health Care, Inc., and
WomenCare, Inc., dba FamilyCare
Health Center*

SANOFI-AVENTIS U.S., LLC,

Plaintiff,

v.

U.S. DEPARTMENT OF HEALTH AND
HUMAN SERVICES, *et al.*,

Defendants.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

Civil Action No. 3:21-cv-634-FLW-LHG

**CONSENT MOTION TO FILE BRIEF AS AMICI CURIAE IN SUPPORT OF
DEFENDANTS BY RYAN WHITE CLINICS FOR 340B ACCESS, LITTLE RIVERS
HEALTH CARE, INC., AND WOMENCARE, INC., DBA FAMILYCARE HEALTH
CENTER**

Ryan White Clinics for 340B Access (“RWC-340B”), Little Rivers Health Care, Inc. (“Little Rivers”), and WomenCare, Inc., dba FamilyCare Health Center (“FamilyCare”) (collectively the “Amici”), by and through undersigned counsel, respectfully request to file a brief as amici curiae in the above captioned case. The Amici support the Defendants’ Opposition to Plaintiff’s Motion for Preliminary Injunction. ECF No. 29. Amici have conferred with the parties, and counsel for all parties have consented to the filing of the attached amicus curiae brief. Amici’s motion should be granted for several reasons: 1) Amici have a special interest in this case through pending 340B administrative dispute resolution (“ADR”) petitions; 2) no party represents the interests of covered entities that participate in the 340B program, such as Amici;

3) Amici can provide the Court with the useful and unique perspective of small, community based 340B covered entities. The Amici focus on one topic in the attached brief: the harms that a preliminary injunction will cause to small, community based 340B covered entities and their vulnerable patients.

RWC-340B is a national, not-for-profit association of clinics that receive funding under the Ryan White Comprehensive AIDS Resources Emergency Act (“Ryan White CARE Act”), Pub. L. No. 101-381, 104 Stat. 576 (codified at 42 U.S.C. §§ 300ff–300ff-140), to provide health care and related support services to individuals living with human immunodeficiency virus/acquired immunodeficiency syndrome (“HIV/AIDS”). Receipt of this funding qualifies the members of RWC-340B to participate in the 340B program as “covered entities.” Clinics funded under the Ryan White CARE Act provide primary medical care, medications, and support services to over half a million underserved and uninsured individuals living with HIV/AIDS. RWC-340B has members in all regions of the United States, including members that operate at least nine clinics throughout New Jersey. RWC-340B’s members are typically small, nonprofit organizations that do not have the financial resources to operate in-house pharmacies and participate in the 340B program by ordering drugs for shipment to contract pharmacies, which dispense the drugs to the members’ patients.

Little Rivers is a not-for-profit health care provider with facilities located in Wells River, Bradford, and East Corinth, Vermont. Little Rivers’ mission is to provide respectful, comprehensive primary health care for all residents in its region, regardless of ability to pay. Little Rivers is certified by the United States Department of Health and Human Services (“HHS”) as a federally qualified health center (“FQHC”), which qualifies Little Rivers to participate as a covered entity in the 340B program. Little Rivers has been registered as a

covered entity in the 340B program since 2006. Statistics from the Health Resources and Services Administration (“HRSA”), the division of HHS that administers FQHC grants, show that Little Rivers served more than 5,500 patients in 2019 and that, of those patients with known incomes, 61.2% had income at or below 200% of the Federal Poverty Level (“FPL”), including 19.48% with income at or below 100% of the FPL. HRSA, *Health Center Program Data for Little Rivers, Patient Characteristics*, <https://data.hrsa.gov/tools/data-reporting/program-data?grantNum=H80CS06658> (last visited Feb. 26, 2021). In 2019, approximately 50% of Little Rivers’ patients were either Medicaid or Medicare recipients and approximately 5% of its patients were uninsured. *Id.* Little Rivers does not operate an in-house pharmacy and participates in the 340B program by using contract pharmacy relationships. Little Rivers filed an ADR petition on February 4, 2021, to contest a drug company’s action to cease shipping 340B drugs to Little Rivers’ contract pharmacies.

FamilyCare is a not-for-profit health care provider with several facilities in West Virginia, including three mobile units and clinics at local schools. FamilyCare’s mission is to make high-quality, whole-person care available to every member of the family and every member of the community. FamilyCare is an FQHC and is eligible to participate as a covered entity in the 340B program by virtue of that designation. FamilyCare has been registered as a covered entity in the 340B program since 2000. According to HRSA statistics, FamilyCare served 32,353 patients in 2019, and of those patients with known incomes, 99.53% have annual incomes at or below 200% of the FPL, including 50.43% with annual incomes at or below 100% of the FPL. HRSA, *Health Center Program Data for WomenCare, Patient Statistics*, <https://data.hrsa.gov/tools/data-reporting/program-data?grantNum=H80CS00827> (last visited Feb. 26, 2021). In 2019, approximately 63% of FamilyCare’s patients were either Medicaid or

Medicare recipients and 7.46% of its patients were uninsured. *Id.* FamilyCare does not operate an in-house pharmacy and participates in the 340B program by using contract pharmacy relationships. FamilyCare filed an ADR petition on February 12, 2021, to contest a drug company's action to cease shipping 340B drugs to FamilyCare's contract pharmacies.

Neither the Federal Rules of Civil Procedure nor the Local Rules of this Court address amicus briefs. Therefore, this Court has “broad discretion” to determine the “extent, if any, to which an amicus curiae should be permitted to participate in a pending action.” *Bryant v. N.J. Dep’t of Transp.*, 987 F. Supp. 343, 346 n. 3 (D.N.J. 1998) (rev’d on other grounds); *see also Yip v. Pagano*, 606 F. Supp. 1566, 1568 (D.N.J. 1985), *aff’d*, 782 F.2d 1033 (3d Cir. 1986). District courts have granted amicus curiae status where (1) the amicus has a “special interest” in the particular case; (2) the amicus’ interest is not represented adequately or at all in the case; and (3) the proffered information is timely and useful.¹ *United States v. Alkaabi*, 223 F. Supp. 2d 583, 592 (D.N.J. 2002). The Amici meet all three standards.

First, the Amici have a “special interest” in this case. *Alkaabi*, 223 F. Supp. 2d at 592. All three Amici are plaintiffs in a lawsuit against several of the Defendants that concerns the ADR regulations that the Plaintiff seeks to enjoin. Amended Compl., *RWC-340B v. Azar*, No. 1:20-cv-02906 (D.D.C. Nov. 23, 2020), ECF No. 21 (stayed Jan. 13, 2021). Moreover, two of the Amici (Little Rivers and Family Care) have filed petitions under the ADR process that Plaintiff seeks to enjoin.

¹ The *Alkaabi* court also examined whether the amicus was partial to a particular outcome in the case, *Alkaabi*, 223 F. Supp. 2d at 592, but this factor is not controlling. The Third Circuit has held that a party seeking to file an amicus brief does not need to be impartial and may have an interest in the outcome of the case. *Neonatology Associates, P.A. v. C.I.R.*, 293 F.3d 128, 131 (3d Cir. 2002) (“Thus, an amicus who makes a strong but responsible presentation in support of a party can truly serve as the court’s friend.”). Additionally, the New Jersey District Court has granted motions to file amicus briefs when the amicus was interested in the outcome of the case. *See Acra Turf Club, LLC v. Zanzuccki*, No. 12–2775, 2014 WL 5465870, at *6 (D.N.J. 2014).

Plaintiff Sanofi Aventis U.S., LLC, (“Sanofi”) has stopped shipping 340B discounted drugs to Little Rivers’ and Family Care’s contract pharmacies. When Sanofi adopted this policy, Amici’s options to vindicate their rights were limited in important ways. First, covered entities are precluded from bringing an action directly against a drug manufacturer to enforce the 340B statute. *Astra USA, Inc. v. Santa Clara Cty., Cal.*, 563 U.S. 110 (2011). Second, Congress had ordered HHS to implement an ADR process to resolve disputes between covered entities and drug companies, but HHS had not yet adopted the final ADR regulations. Therefore, the Amici’s only recourse was to file suit against several of the Defendants to seek an order directing them to promulgate ADR regulations or to otherwise remedy the drug companies’ actions. HHS subsequently issued the ADR regulations that are the subject of plaintiff’s motion for preliminary injunction. 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80,632 (Dec. 14, 2020).

On the same date that the ADR regulations became effective, the parties in *RWC-340B v. Azar* agreed to stay the case to allow Amici to pursue ADR claims against drug manufacturers. Joint Mot. to Stay, *RWC-340B v. Azar*, No. 1:20-cv-02906 (D.D.C. Jan. 13, 2021), ECF No. 58. Significantly, the parties in *RWC-340B v. Azar* recently notified the United States District Court for the District of Columbia of the instant action and agreed to file a further status report the earlier of April 19, 2021, or within five business days of any an injunction of the ADR regulations. Joint Status Report, *RWC-340B v. Azar*, No. 1:20-cv-02906 (D.D.C. Feb. 16, 2021), ECF No. 59. Amici Little Rivers and FamilyCare have already filed ADR Petitions and amicus RWC-340B is evaluating whether to file an ADR petition.² In addition, the United States

² Little Rivers and FamilyCare have filed ADR petitions against another manufacturer that has, like Plaintiff, also refused to provide 340B discounts through contract pharmacies. Decisions issued through the ADR process are precedential. 42 C.F.R. § 10.20, 10.24(d). Therefore, this Court’s decision will undoubtedly have an impact on the ADR proceedings for Little Rivers and

District Court for the Northern District of California recently ruled that that the 340B statute requires that disputes between covered entities and manufacturers must first be adjudicated through the ADR process. *Am. Hosp. Ass'n v. Dep't of Health & Human Servs.*, No. 4:20-CV-08806-YGR, 2021 WL 616323 (N.D. Cal. Feb. 17, 2021), ECF No. 91. The Amici, therefore, have a significant interest in whether this Court enjoins the ADR regulations because those regulations implement a process that may be the only way Amici, and other 340B covered entities, can obtain a remedy against the Plaintiff. The Court should grant Amici's motion because the Amici have a direct interest in both their own lawsuit as well as their pending ADR petitions, and the decision on Plaintiff's motion for preliminary injunction will materially affect those interests. Access to the ADR process is essential because Sanofi's unlawful contract pharmacy policy deprives discounts to disadvantaged patients and prevents covered entities from funding necessary health care services.

Second, the Amici are not represented adequately in this case. *Alkaabi*, 223 F. Supp. 2d at 592. Clearly, Plaintiff does not represent Amici's interests because Plaintiff refuses to ship 340B discounted drugs to Amici's contract pharmacies and is now seeking to enjoin the ADR procedures that Amici are already using. The Defendants also do not adequately represent Amici's interest. The Defendants administer the 340B program and the ADR process but are not covered entities on the front lines of furnishing health care to the disadvantaged. While Amici support the Defendants' opposition to the Plaintiff's motion for preliminary injunction, and generally the arguments in Defendants' opposition brief, Amici are currently plaintiffs in a lawsuit against several of the Defendants concerning both the ADR regulations and the contract pharmacy program. Amended Compl., *RWC-340B v Azar*, No. 1:20-cv-02906 (D.D.C. Nov. 23,

FamilyCare.

2020), ECF No. 21, (stayed Jan. 13, 2021). In addition, the proposed intervenors in the instant action, if granted intervention, would not adequately represent the interests of Amici because the proposed intervenors do not seek to intervene regarding the ADR regulation at issue in Plaintiff's motion for preliminary injunction. Mem. Law Supp. Mot. to Intervene 7, ECF No. 34.

Third, the Amici can provide the Court with useful and unique information in the instant case, and that information is timely. *Alkaabi*, 223 F. Supp. 2d at 592. Congress intended the 340B program to allow covered entities to “stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” H.R. Rep. No. 102-384(II), at 12 (1992); *see also Cares Cmty Health v. U.S. Dep’t of Health & Human Servs.*, 944 F.3d 950, 955 (D.C. Cir. 2019) (340B savings “help safety-net providers fund the uncompensated care they supply and expand the services they offer.”). Neither the Plaintiff nor the Defendants in this case are 340B covered entities. The Amici can, therefore, provide the Court with the perspective of the entities that the 340B program was intended to benefit, a perspective that neither the Plaintiff nor the Defendants can possibly have because they are not 340B covered entities. This motion and the attached amicus curiae brief are also timely. Because the Federal Rules of Civil Procedure and the Local Rules of this Court do not address amicus briefs, Rule 29 of the Federal Rules of Appellate Procedure is instructive. Rule 29(a)(6) provides that an amicus brief and motion are timely if filed no later than seven days after the principal brief of the party supported. Fed. R. App. P. 29(a)(6). The Amici are supporting Defendants’ opposition to the Plaintiff’s motion for preliminary injunction, which Defendants filed on February 25, 2021, and the Amici filed this motion with attached amicus curiae brief within seven days.

Therefore, the Amici respectfully move the Court for leave to file the attached amicus

curiae brief and accompanying exhibits.

Respectfully submitted,

/s/ Steven A. Haber

Steven A. Haber (I.D. #03946-1988)
OBERMAYER REBMANN MAXWELL &
HIPPEL LLP

1120 Route 73, Suite 420

Mt. Laurel, NJ 08054

Tel. (856) 857-1422

Fax (856) 482-0504

Steven.Haber@Obermayer.com

/s/ Ronald S. Connelly

Ronald S. Connelly

D.C. Bar No. 488298 (pro hac vice application
pending)

POWERS PYLES SUTTER & VERVILLE, PC

1501 M Street, N.W., 7th Floor

Washington, DC 20005

Tel. (202) 466-6550

Fax (202) 785-1756

Ron.Connelly@PowersLaw.com

Attorneys for Amici Curiae

Dated: March 4, 2021